

YPL-0061

**REMARKS**

In response to the Office Action dated June 21, 2005, Applicants respectfully request reconsideration based on the above claim amendments and the following remarks. Applicants respectfully submit that the claims as presented are in condition for allowance.

Upon entry of this amendment, claims 1-11 are present for consideration. Applicants amended claims 1-2 and 10-11 and have added no new claims. Antecedent basis for amendments to claims 1-2 and 10-11 is found in the specification at least at p.4, lines 19-20, and p. 4, lines 25-28, respectively. No new matter has been introduced by these amendments.

As explained below, Applicants believe they have placed the claims in condition for allowance according to 37 C.F.R. 1.116, and respectfully request reconsideration and allowance of the claims in view of the above amendments and the following remarks.

***Claim Objections***

Claims 10 and 11 stand objected to for informalities. The Examiner stated that the element "predetermined frequency" is unclear by reading the claims. Applicants have clarified claims 10 and 11 by amending both claims to include the phrase "alternating current voltage" to clarify the meaning of the element "predetermined frequency". Therefore, Applicants respectfully request reconsideration and withdrawal of the objection to claims 10 and 11.

***Claim Rejections Under 35 U.S.C. §112***

Claims 1-11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection of claims 1-11 under 35 U.S.C. § 112, second paragraph, for the following reasons.

The Examiner states that the previously amended claim 1 describes a PCR reaction performed in the absence of an ionically-labelled probe, allegedly without providing any (1) indication of steps taken to perform PCR in the absence of an ionically-labelled probe and (2) specific examples of an ionically-labelled probe.

YPL-0061

Applicants have amended claims 1 and 2 to clarify the claimed subject matter. As a result of these amendments, the examiner's rejection of claims 1-11 as being indefinite regarding the phrase "an ionically-labelled probe" is now moot. Applicants therefore respectfully request reconsideration and withdrawal of the rejection of claims 1-11 under 35 U.S.C. §112, second paragraph.

***Claim Rejections Under 35 U.S.C. §102***

The Office Action states that claims 1-6 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Blackburn et al., U.S. 6,264,825 (hereinafter "Blackburn"). Applicants respectfully traverse the rejection of claims 1-6 as being anticipated under 35 U.S.C. §102(b) for the following reasons.

The Examiner states that Blackburn discloses a method for detecting a PCR product comprising providing at least a pair of electrodes in a PCR solution containing vessel; performing PCR in the absence of an ionically labeled probe; producing an electric field between the electrodes; and measuring a change in a dielectric property in a PCR solution. In particular, the Examiner notes that Blackburn never discloses anything about using an ionically labelled probe.

According to MPEP 2131, to anticipate a claim, a reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. "Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)." Further, the elements must be arranged as required by the claim, but this is not an *ipse dixit* test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)..

Applicants' amended claim 1, with emphasis added, is reproduced below:

1. A method for detecting a polymerase chain reaction (PCR) product, comprising:  
providing at least a pair of electrodes in a PCR solution-containing vessel;  
performing PCR;  
producing an electric field between the electrodes; and  
measuring a change in a dielectric property in the PCR solution,

YPL-0061

wherein the measuring is performed in the absence of an additional probe for generating an electrical signal.

Blackburn discloses compositions and methods to detect a target analyte in a sample, e.g., a polymerase chain reaction sample. The method of Blackburn et al. uses a detection electrode comprising a covalently attached capture ligand (Blackburn et al. col. 2, lines 15-18) or a self-assembled monolayer with a capture ligand (col. 2, lines 61-63).

Applicants' claim 1 is directed to a method for detecting a polymerase chain reaction (PCR) product in the absence of any additional probe for generating an electrical signal. Unlike the methods disclosed by Blackburn, Applicants' invention does not require use of a capture ligand for measuring a change in a dielectric property in the PCR solution over the course of the polymerase chain reaction. Applicants believe that their invention differs from Blackburn, as well as other references cited by the Examiner and the prior art known to Applicants, in that the invention of claim 1 comprises a step of measuring the change in a dielectric property between the starting reactants and the resultant products of the reaction *directly*, in real-time, without requiring any additional probe in the solution or on the electrodes for generating the measured electrical signal. Figures 8-14 of the instant application demonstrate that reaction progress may be directly measured in solution as a change in a dielectric property between starting reactants and resultant products over the course of the polymerase chain reaction. Applicants believe this is the first demonstration that no additional probe need be added to generate the electrical signal for such a real-time determination of polymerase chain reaction progress in solution.

Therefore, Blackburn does not anticipate claim 1 because the methods of Blackburn require an additional probe to allow electronic measurement of the target analyte in a sample, such as a capture ligand covalently attached to the detection electrode or a self-assembled monolayer on the detection electrode with a capture ligand (col. 2, lines 15-18; col. 2, lines 61-63), while claim 1 as amended explicitly discloses that the measuring is performed in the absence of an additional probe for generating an electrical signal.

Further regarding the Claim 1 rejection as anticipated by Blackburn, the Examiner recited several paragraphs of Blackburn: col 88, lines 5-7 for a method for detecting a PCR product; col, 88 lines 8-15 for a pair of electrodes; col 90, lines 38-42 for a PCR solution containing vessel; col

YPL-0061

87, line 60 - col 88 line 15 for performing PCR; col 9, lines 7-11 for non-ionic nucleic acid; col 83, line 65 - col 84, line 14, and col 83, line 49-55 for measuring a change in a dielectric property in a PCR solution. However, the citations are independent and separate from each other. *Therefore, the elements cited by the Examiner are not arranged as required by Claim 1.* For example, col 88 lines 8-15 reads "*Finally, the nucleic acid attached to the electrode via a conductive polymer may be one PCR primer, with addition of a second primer labeled with a ETM. Elongation results in double stranded nucleic acid with a ETM and electrode primer covalently attached. In this regard, the present invention is used for PCR detection of target sequence*". The Examiner cited only "a pair of electrodes" as an element to anticipate Claim 1 from the above paragraph. However, the electrode is not arranged in the same manner as it is in Claim 1 rather; it is linked to a PCR primer, i.e., a probe which is complementary to the PCR product, via a conductive polymer.

In view of the foregoing, the subject matter of Claim 1 is not anticipated by Blackburn since the Examiner has failed to provide evidence that all the elements recited in Claim 1 are found and arranged in the manner required by Claim 1 in Blackburn.

Similarly, Blackburn does not anticipate claim 2 because claim 2 states that the electrode does not comprise an attached probe for generating an electrical signal that binds to reactants or products of the PCR, while the methods of Blackburn require an additional probe (capture ligand) to allow electronic measurement of the target analyte in a sample (col. 2, lines 15-18; col. 2, lines 61-63).

As claims 3-6 depend from claim 1 and must include all the limitations of the base claim, Blackburn also cannot anticipate claims 3-6. Applicants therefore request reconsideration and withdrawal of the rejection of claims 1-6 under 35 U.S.C. § 102(b) as being anticipated by Blackburn.

### **Conclusion**

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If the Examiner believes that a telephone conference with Applicants' attorneys would be

YPL-0061

advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned.

In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicants' agent hereby authorizes that such fee be charged to Deposit Account No. 06-1130.

Respectfully submitted,  
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